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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,026	10/10/2001	Paul P. Tamburini	96-223-ZZ	7892
20306	7590	07/01/2004	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			LIU, SAMUEL W	
300 S. WACKER DRIVE			ART UNIT	
32ND FLOOR			PAPER NUMBER	
CHICAGO, IL 60606			1653	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/974,026

**Applicant(s)**

TAMBURINI ET AL.

**Examiner**

Samuel W Liu

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☒ Claim(s) 13 and 15-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/22/02 & 1/15/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***DETAILED ACTION***

*Status of the claims*

Claims 12-17 are pending.

Applicants' preliminary amendment filed 25 March 2002, which cancels claims 1-11 and adds claims 12-17 have been entered. Also, applicants' request for extension of time of one month (filed 1 May 2002) has been entered.

The pending claims 12-17 are examined in this Office action.

***IDS***

The references lists in the IDS filed 22 March 2002 and the IDS filed 15 January 2004 have been considered by Examiner.

***Specification/Claim/ Objections***

The disclosure is objected to because of the following informalities:

In page 6, line 35, "SEQIDNO:7" should be changed to "SEQ ID NO:7". The same change should be made throughout the specification.

In page 8, line 25, "SEQ ID NO:45, 2" should be changed to "SEQ ID NOs: 2 and 45".

In page 14, line 12, "PCR" should be spelled out in full for the first instance of use.; See also, page 15, line 23, "SDS-PAGE".

In page 55, line 30, "33  $\mu$ M final" should be changed to "33 $\mu$ M final concentration".

In claim 13, "SEQ ID NO:9, 32, 44, 46, 48, 51, and 75" should be changed to "SEQ ID NOs: 9, 32, 44, 46, 48, 51 and 75".

In claim 15, "a protein that is: (a) glycosylated; or (b) contains ..." should be changed to "a protein that: (a) is glycosylated; or (b) contains ...".

In claim 16, "preparing a protein ..." should be changed to "producing a protein ...".  
Because preparing a protein can refer to formulating or isolating or modifying a protein.

In claim 17, "a protein is: (a) glycosylated; or (b) contains ..." should be changed to "a protein that: (a) is glycosylated; or (b) contains ...".

The abstract of the disclosure is objected to because the current application does not provide abstract in one paragraph at a separated page. See MPEP § 608.01(b).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, the first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim 12 does not describe biological function of (i) the nucleotide sequence of SEQ ID NO:8. Note that the specification (at page 7) sets forth pre-maturely terminated fragment (amino acids 1-92) is a functional protein; however, there is no demonstration by working example(s) for this regard. (ii) At page 6, the specification sets forth that SEQ ID NO:5

(amino acids 11-61) and SEQ ID NO:7 (amino acids 106-156), which are the fragments derived from the full-length sequence of SEQ ID NO:52. Yet, the specification does not describe the biological functional by demonstrating that the said fragments have the same function as the full-length sequence of SEQ ID NO:52 from which they derived. Note that the specification does not provide working example(s) or factual evidence in this regard. Application has disclosed only the full-length sequence of SEQ ID NO:52 and those sequences comprising the full-length polynucleotides which encode human placental Kunitz proteins comprising two serine protease inhibitor domain, and disclosed and demonstrated that (a) the functional fragment (amino acids 102-159) of SEQ ID NO: 6 sequence (see Examples 1 and 5) and the sequences comprising the functional fragment thereof, and (b) the functional fragment (amino acids 7-64) of SEQ ID NO: 4 sequence (see Example 4) and the sequences comprising the functional fragment thereof. Application has not disclosed the biological activity of the fragment of SEQ ID NO: 5 (amino acids 11-61) and the fragment of SEQ ID NO:7 (amino acids 106-156), both which are structurally distinct from the above-mentioned functional fragments of SEQ ID NOs: 4 and 6.

Thus, the instant invention has not been described in such a way that it is clear that the applicant invented what is claimed, and thus, does not fulfill the enablement criteria. Applicants are not in possession of the nucleic acid sequences of SEQ ID NOs: 5, 6 and 8.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons

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of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

*SWL*

Samuel Wei Liu, Ph.D.  
Art Unit 1653, Examiner  
June 17, 2004

*Karen Cochrane Carlson*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER